

### **Remarks**

Claims 2, 4-5 and 33-34 are pending. Applicants have added new Claim 35, which is dependent from Claim 33. Dependent Claim 35 is fully supported by the specification on page 14 and, as a result, no new matter has been added. The Applicants have amended Claim 5 to place it in the proper dependent form to further define the subject matter of the previous claim. Specifically, the Applicants have amended Claim 5 so that the sequence as described in independent Claim 4 is directed to the sequence between amino acids 23 and 395 of SEQ ID No: 1. As a result, Claim 5 now provides a narrower range of amino acids than the independent claims from which it depends.

Applicants have amended Claims 33 and 34 and added Claim 35 to remove the use of the term “vaccine”, and as a result have clearly defined the unique immunogenic properties of the Applicants’ protein.

### **Claim Rejections under 35 U.S.C. § 102**

Applicants note with appreciation the withdrawal from rejection of Claims 1, 4 and 33-34 as being anticipated by Keohane et al.

Claims 2, 4-5 and 33-34 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Delbac et al.

Applicants claims are drawn to a microsporidian polar tube protein having a defined amino acid sequence, showing as SEQ ID No: 1. SEQ ID No: 1 shows a specific location and orientation of 395 amino acids of the Applicants’ polar tube protein, as well as, the specific DNA sequence associated with the Applicants’ polar tube protein. The Applicants acknowledge that Delbac et al. discloses a polar tube protein having 395 amino acids, as well as a defined molecular mass. However, the Applicants respectfully submit that nowhere in Delbac et al. is the sequence

orientational, and/or the order of the 395 amino acids given. Delbac et al. does not show which 395 amino acids comprise the polar tube protein, the order of those amino acids, or the DNA sequence and codons which code for the amino acid of the polar tube protein. Specifically, SEQ ID No:1 identifies both the amino acids and the codons which code for those amino acids.

In light of the Applicants well-defined sequence, we invite the Examiner's attention to *In re Deuel*, wherein the court held that the rejection of claims drawn to a particular DNA sequence is improper when the reference used in the prior art rejection fails to teach the DNA molecules.

*In re Deuel* is analogous to this case. The court in *In re Deuel* noted that:

While the general idea of the claimed molecules, their function, and their general chemical nature may have been obvious Bohlen's teachings, and the knowledge that some genes existed may have been clear, the precise cDNA molecules of Claims 5 and 7 would not have been obvious over the Bohlen reference because Bohlen teaches proteins, not the claimed or closely related cDNA molecules. The redundancy of the genetic code precluded contemplation of or focus on the specific cDNA molecules of Claims 5 and 7... Similarly, knowledge of a protein does not give one a conception of a particular DNA encoding it. Thus, a *fortiori*, Bohlen's disclosure of the N-terminal portion of a protein, which the PTO urges is the same as HBGF, would not have suggested the particular cDNA molecules defined by Claims 5 and 7. This is so even though one skilled in the art knew that some DNA, albeit not in purified and isolated form, did exist. The compounds of Claims 5 and 7 are specific compounds not suggested by the prior art.

Likewise, in this case, Delbac et al., while describing the protein and indicating the number of base pairs associated with the protein, utterly fails to disclose the particular DNA sequences and amino acid sequence associated with the protein that the Applicants have claimed with both an amino acid and DNA sequence. Consequently, one skilled in the art, when reading Delbac et al. without the hindsight of the disclosure in the Applicants' specification, would have no knowledge of the particular amino acid sequence, or the DNA which encodes that amino acid sequence.

As was stated in *In re Bell* 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and reiterated in *In re Deuel*, the existence of a general method of isolating DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggest the claimed DNA. This holding is applicable to this prior art rejection, which fails to articulate prior art that discloses the Applicant's DNA and/or amino acid sequences.

The Applicants have isolated, purified and completely sequenced the polar tube protein of *E. cuniculi*. Specifically, the Applicants have determined the polar tube protein's particular amino acid and DNA sequence. Nowhere in Delbac et al is there such a disclosure. In view of the fact that Delbac et al. fails to disclose specific sequence data, the Applicants respectfully submit that "the mere fact that a certain thing may result from a giving set of circumstances is not sufficient to establish inherency." *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1991). Thus, the Applicants respectfully submit that the sequence described in Claim 4 was not inherent in light of the teachings described in Delbac et al.

In view of the foregoing, Applicants respectfully submit that the Claims are now in condition for allowance, which action is respectfully requested.

Respectfully submitted,



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